AUG 0 6 2002

K013999

LODOX SYSTEMS (PTY) LTD
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South Africa
2146

Registration Number 2000/024615/07

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510(K) SUMMARY

[As required by 21CFR807.92]

5.1 Date Prepared [21CFR807.92(a)(1)]

November, 2001

5.2 Submitter's Information [21CFR807.92(a)(1)]

Company Name:	Centric Capital Ventures LLC (a Delaware Limited Liability Company)
Establishment Registration Number:	13-4104540
Street Address:	177 East 79th Street, Suite 4
City:	New York
State/Province:	New York, 10021
Country:	USA
Telephone:	212-439-0746
Facsimile:	212-452-0756
Contact Person:	Bradley Sacks
Contact Title:	Managing Partner
Contact email:	bradsacks@earthlink.net

5.3 Trade Name, Common Name, Classification [21CFR807.92(a)(2)]

Trade Name:	Lodox
Common Name:	Digital Radiography System
Classification Name:	Solid State X-ray Imager (SSXI)
Device Class:	Class II
Product Code:	90MQB

5.4 Identification of Predicate Device(s) [21CFR807.92(a)(3)]

Equivalency is based on the Elscint EXCEL 2000 ELITE CT system (K884671) and the Siemens Polydoros 80 system (K950883) and bucky (x-ray film holder) using conventional radiographic film (21CFR892.1840).

5.5 Description of the Device [21CFR807.92(a)(4)]

Lodox is a whole-body x-ray scanner that produces x-ray images that can be used for diagnostic purposes. It is an optical-based digital x-ray imager. It works by converting incident x-ray energy to visible light by use of a fluorescent screen optically coupled to a number of CCD cameras, which produce a digital image.

The captured diagnostic image is stored in a database and is displayed on a high-resolution, medical-quality monitor, where the diagnosis can be performed.

The diagnostic image can be transmitted through a DICOM 3.0 compatible digital network for printing.

The imaging area can be set from 100 mm x 100 mm to 1800 mm x 680 mm on a special purpose patient trolley.

5.6 Intended Use [21CFR807.92(a)(5)]

Lodox is a digital x-ray imager intended as a replacement for x-ray film for general human radiography (excluding fluoroscopy, angiography, and mammography). It is specifically aimed at emergency room use.

Lodox allows radiographic exposures of the whole body including skull, spinal column, chest, abdomen, and extremities. Radiographic exposures may be taken of a patient lying on the patient trolley in any angle from the Anterior-Posterior view to the lateral view, or with the patient in the standing or prone positions.

5.7 Technological Characteristics [21CFR807.92(a)(6)]

Feature	Lodox	Elscint EXCEL 2000 ELITE CT	Siemens Polydoros 80	Bucky with Film / Screen
510(k) Regulation	Pending	K884671	K950883	892.1840
Intended Use	General Human Radiography			
Fluorescent screen to convert x-rays to light	Yes	Yes	No	Yes
Whole body radiograph	Yes	Yes [1]	No	
Whole body exposure [2]	25 μGy	80,5 μGy [1]	-	
Chest exposure [3]	0,21 mGy	-	2,57 mGy	
CCD to capture image	Yes	Yes	No	
CCD Pixel Size	26 x 26 μm	Not Available	-	
Half-Value Layer	4,35 mm	-	4,73 mm	
Signal-to-Noise Ratio	2,57	-	2,16	
Modulation Transfer Function [4]	1,67 lp/mm [5]	-	2,34 lp/mm [4]	
Detective Quantum Efficiency	TBD [6]	-	TBD [6]	
External Connectivity	DICOM 3.0	None	None	
Image Storage	Hard Drive	Hard Drive	X-ray film	

NOTE

1. CT in scan mode.
2. Measured on bed with no patient present.
3. An average taken of 10 chest x-ray cases.
4. Measured on bed, along its width, at 3% contrast.
5. In normal resolution mode (5 x 5 binning) and perpendicular to scan direction.
6. Work Group (WG33) in IEC/SC62B is currently developing a new IEC standard for measurement of the DQE of digital x-ray imaging detectors. This is due to be published within the first quarter of 2002. Lodox DQE performance will be determined according to this standard once it is published.

5.8 Non-clinical Testing [21CFR807.92 (b)(1)]

Lodox uses a fluorescent screen of the type used in film/screen radiography to convert x-rays to light. A high-resolution, CCD-based, sensor captures this light.

To verify the spatial resolution and determine its equivalence to film, tests were performed using line-pair resolution and high and low contrast targets. Resolution was found to substantially equivalent to the predicate.

5.9 Clinical Testing [21CFR807.92 (b)(2)]

In an image quality study, 39 human subjects were x-rayed both conventionally and with Lodox. A range of anatomy was covered representative of general radiography. The results were examined by a panel of two radiologists and found substantially equivalent to film.

5.10 Conclusions [21CFR807.92 (b)(3)]

Images taken using the digital technology of Lodox were substantially equivalent to images taken on the Elscint EXCEL 2000 ELITE CT system based on the following:

1. Whole-body radiographs could be taken on both systems.

Images taken using the digital technology of Lodox were substantially equivalent to standard film images based on the following:

1. The results from studies showed that the digital images were comparable to film.

2. Laboratory test results also supported the equivalence to standard film images shown in clinical studies. This clinical outcome supported the diagnostic imaging quality of the digital system as being equal to film/screen.

It was concluded that Lodox is equivalent to the Elscint EXCEL 2000 ELITE CT system (K884671) and the Siemens Polydoros 80 system (K950883) and bucky (x-ray film holder) using conventional radiographic film (21CFR892.1840) based upon the following criteria:

- Lodox has the same intended use as the predicate devices; and,
- Lodox has radiographic performance equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Lodox Systems (Pty) LTD
% Mr. Bradley Sacks
Managing Partner
Centric Capital Ventures, LLC
177 East 79th Street, Suite 4
NEW YORK NY 10021

Re: K013999
Trade/Device Name: Lodox Whole Body X-ray Scanner
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomographic x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: May 10, 2002
Received: May 13, 2002

Dear Mr. Sacks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. SECTION D - STATEMENT OF INDICATIONS FOR USE

Applicant	**Lodox Systems (Pty) LTD**
510(k) Number (if known)	**N/A** K013999
Device Name	**Lodox X-ray Scanner**

Indications for use:

The Lodox whole-body x-ray scanner is mainly intended for use in trauma wards where multiple injuries can be medically diagnosed in a very short time. It can also be used for normal x-ray examinations as is currently practised with general-purpose single-shot x-ray machines. A full image area is 1800 mm by 680 mm, and can be reduced to any size down to 100 mm by 100 mm anywhere within the image area.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013999